

Kindly cancel claim 18.

REMARKS

The applicant is pleased to note that the rejection over Velucchi et al. has been withdrawn and that the rejection of claims 1-10, 12-16 and 51-53 under 35 U.S.C. §112, second paragraph has been withdrawn. The objection to the disclosure has also been withdrawn. Claims 3-52 were noted as being indefinite in the use of the term "of the formula" rather than the term "comprising". By this Amendment, the term "comprising" has been introduced into claims 3-52 and for this reason, it is requested that this ground of objection be withdrawn.

Reconsideration and allowance are respectfully requested in light of the foregoing amendments and the following representations.

On page 3 of the Office Action dated April 12, 2000, the Examiner rejected claims 1-34 and 51 under 35 U.S.C. 102(b) as being anticipated by Porro WO 95/03327 ('327).

Reconsideration is requested.

Porro '327 discloses and claims the use of novel peptides as treatment for septic shock. The peptides may be administered either parenterally or intravenously. A method of preparing a vaccine based on stoichiometric amounts of Lipid A or LPS is described on page 7, lines 14 to 20. Applicant respectfully submits that the instant invention is distinguishable from Porro '327 in that the claims of the present application point out that the invention provides a novel vaccine which is based on the use of a stoichiometric excess of peptide relative to the lipid moiety. This provides more than the one-to-one ratio of LPS to peptide, as described in Porro '327.

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On page 4 of the Office Action the Examiner rejected Claims 1-54 under the judicially-created doctrine of double patenting over claims 1-16 of Porro '933 and Claims 1-11 of Porro '186. Applicant respectfully requests reconsideration.

Porro '933 claims peptides and peptide compositions. There is no mention of vaccines in the claims of this patent. For this reason, there can be no obviousness double patenting and it is requested that this ground of rejection be withdrawn.

On page 4 of the Office Action, the Examiner rejected Claims 1-54 under U.S.C § 112, as not being enabling for the use of peptides as a vaccine preparation. Applicant respectfully requests reconsideration.

Enablement for making a complex which is useful as a vaccine is provided at page 6, line 24 to page 7 line 3. The preferred embodiment is recited as being preferably 250 to 2500 units peptide to 1 unit bacterially-derived LPS. Preparation of a protein-conjugated LPS for use in the vaccine is taught on page 15 lines 6 forward, and a preferred ratio of LPS to BSA is taught on page 7 lines 1-3. Details of the LPS/peptide reaction is described on page 13 lines 15-18 and page 15, line 33 forward.

The practice of the invention is taught on page 13 lines 18-29 of the specification and a suggested regimen of initial dose plus booster doses is taught on page 13 lines 30-33. Successful in-vivo experimental use of the invention as a vaccine in mice is reported in Figures 6a and 6b as discussed on page 5 of the application. This data establishes the usefulness and operability of the applicant's invention. For these reasons, it is requested that this ground of rejection be withdrawn.

On page 5 of the Office Action the Examiner noted that Bone (JAMA 276:565-66, 1996) points out once a patient begins to develop very high systemic levels of pro-inflammatory mediators the resultant clinical syndrome of sepsis becomes very difficult to treat. The present invention provides a vaccine which is administered prophylactically and the comments of Bone do not related to vaccines but rather to chemotherapeutic regimens or antitoxin type therapy. Applicant therefore respectfully submits that prevention of sepsis through the LPS based vaccines of this Application has been

demonstrated as a successful method as indicated by the in-vivo studies reported in the specification and in Figures 6a and 6b.

New claim 55 is canceled claim 18 in independent form. The text of new claim 56 is based on the specification at page 5 where non-typable H. influenzae is disclosed as a suitable LPS producing species of bacteria.

Applicant respectfully submits that based on the amendments and arguments presented that all the claims are in condition for allowance. Any additional required fee may be charged to Deposit Account No. 08-1540.

Early and favorable action is earnestly requested.

Respectfully submitted,



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